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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,377	04/24/2000	KLAUS SOMMERMEYER	6-1037-001	1845
803	7590	04/08/2004	EXAMINER	
STURM & FIX LLP 206 SIXTH AVENUE SUITE 1213 DES MOINES, IA 50309-4076			MAIER, LEIGH C	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/485,377	<b>Applicant(s)</b> SOMMERMEYER ET AL.	
	<b>Examiner</b> Leigh C. Maier	<b>Art Unit</b> 1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 2/19/04
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Claims***

Claims 6 and 20 have been amended. Claims 21 and 22 have been added. Claims 1-22 are pending. Upon review of the record, finality has been withdrawn and prosecution has been reopened.

Any rejection or objection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Objections***

Claim 22 is objected to because of the following informalities: "least" is misspelled. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112 – 2<sup>nd</sup> paragraph***

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claim 1, Applicant has emphasized the importance of the limitation requiring that the starch be in solution, differentiating it from processes comprising a starch slurry or suspension. It is not clear if this limitation is meant to also limit the starch substrate to a modified one that is soluble in the aqueous hydrolysis solution or if the claim still contemplates the full range of starch substrates, including insoluble, unmodified starches.

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Regarding claim 2, the claim recites the limitation "the reaction stage" which has no antecedent basis in claim 1.

Regarding claim 3, the claim recites a tubular reactor with mixing elements. All elements in dependent claims must also be in the independent claim, but the main claim requires that the reaction is essentially free of mixing. It appears that what Applicant intends is a "main hydrolysis" that is done essentially free of mixing which is followed by a "fine hydrolysis" which allows mixing. Applicant might consider revising claim 1 to recite a "method for the continuous production . . . the method comprising a main hydrolysis wherein the starch, etc." and also revise claim 3 to recite "the method of claim 1 further comprising a fine hydrolysis. . .etc."

Regarding claim 4, the claim recites "the product to be hydrolyzed." The use of the term "product" is typically thought of as the entity that is ultimately prepared in the process. The use of "product" to (apparently) refer to a reaction substrate renders the claim vague and indefinite. The Applicant might consider using "starch" instead.

Regarding claim 5, the claim recites "wherein tubular reactors are tempered." However, these recited reactors have no apparent connection with the process recited in claim 1, rendering the claim vague and indefinite. The Applicant might consider an amendment to claim 1 reciting "[starch] is continuously conveyed through at least one reactor. . ." and to claim 5 reciting "wherein the reactor(s) are tubular reactor(s) that are tempered. . ."

Claim 8 has the same problem as claim 3, but would be remedied by amending claim 3 as suggested above.

Regarding claim 9, the claim recites "wherein partially broken down starch [apparently the eventual product of claim 1] is ethoxylated continuously with ethylene oxide. . ." and the

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product of this step is acidified and “the main hydrolysis is carried out . . .” It appears that this claim contemplates a first hydrolysis, ethoxylation, and a second hydrolysis. However, it is not clear which hydrolysis is the antecedent for “the main hydrolysis” recited in this claim.

Regarding claim 14, this claim has the same problem with indefinite antecedent for “main hydrolysis” as in claim 3 above. The applicant might consider an amendment similar to that suggested for claim 3.

Claim 16 has the same problem with the use of “product” when apparently the starch substrate is intended, as discussed in claim 4 above.

***Claim Rejections - 35 USC § 112 – 1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 8-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for modified starches which are soluble in the aqueous hydrolysis solution, does not reasonably provide enablement for insoluble, unmodified starches. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

As discussed above, it may be that when Applicant amended the claims to require a solution and preclude the use of a suspension, the intent was to also limit the starch substrates to those that are soluble in the aqueous hydrolysis solution, or if the full range of starches are still contemplated. If it is the latter, the specification does not provide enablement for this sub-set of

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starches. The only working example disclosed comprises a modified starch that is soluble in the hydrolysis reaction mixture. However, Applicant emphasizes purported unexpected results in conducting the hydrolysis on a *solution*. As is seen in SOMMERMEYER (col 4, lines 8-15) and KOMAI both disclose the acid hydrolysis of unmodified starch, wherein the starch reaction mixture is a suspension. Hydrolysis of a starch suspension appears to be the standard in the art. Without further guidance, one of ordinary skill would not be able to use the invention commensurate in scope with these claims and attain these unexpected results without undue experimentation at great expense.

***Claim Rejections - 35 U.S.C. § 103***

Claims 1-8 and 10-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over SOMMERMEYER et al (US 5,218,108) in combination with KOMAI et al (US 3,446,664).

The claims are drawn to a process for the continuous production of starch hydrolyzates wherein the solution to be hydrolyzed is conveyed against the force of gravity through a vertically arranged, one or more tubular reactor(s), essentially free of mixing. This is apparently the "main hydrolysis." It appears that dependent claims are drawn to hydroxyethylation of hydrolyzates and/or further hydrolysis, or "fine hydrolysis," that does allow for mixing. Also claimed is an apparatus for the process having the following required components: (1) feeding device for starch solution; (2) container for a hydrolyzing agent; (3) mixing and heating station; (4) pump arrangement; (5) at least one reactor; (6) conduit; and (7) neutralization station. A dependent claim adds (8) tempering unit(s) for the reactor(s).

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SOMMERMEYER teaches the preparation of hydroxyethyl starch comprising the following steps: (See all of col 4-5)

1. A first hydrolysis of a starch in an aqueous MeOH/1% HCl suspension at 30°-50°C.
2. Neutralization with 1N NaOH and cooling to room temperature.
3. Hydroxyethylation of the partially broken down starch with ethylene oxide in 1N NaOH.
4. A second hydrolysis in an aqueous acidic solution at 40°-70°C.
5. Neutralization with NaOH and cooling.

The reference describes a starch of 20 million D reduced to several million D. See col 3, lines 3-7. This suggests a hydrolysis in the range recited. The reference further teaches the use of the starch hydrolyzates produced as plasma expanders. See col 3, lines 63-68. The reference further teaches that waxy starches are the preferred substrate. See paragraph bridging col 2-3.

SOMMERMEYER does not teach a continuous process or the use of an apparatus described in the claims.

KOMAI teaches an apparatus for continuous acid hydrolysis of starch. See Fig. 1 - the numerals in boldface refer to the components in the figure. The apparatus comprises a (2) container **13**; (3) mixing and heating station **17**; (4) a metering pump **14**; (5) reactors **18, 19**, and **20**; (6) conduits connecting reactors **29, 30**; and (7) neutralization station **22**.

KOMAI teaches conveyance of the hydrolysis reaction mixture through a plurality of vertically arranged tubular reactors against the force of gravity. The reactors have an inlet tube placed at the bottom and an outlet tube at the top. Several flow routes are outlined at col 4, lines 43-61. Routes 1-3, 5, and 6 exemplify exclusively upward flow through the reactors. The reference teaches that upward flow cancels out temperature drops due to cooling and consequent reduced flow rate near the wall surface. See col 4, lines 15-18.

KOMAI is silent regarding whether or not the reaction is conducted essentially without mixing. However, the reference teaches that it is desirable to maintain uniform flow and minimize turbulence. See col 4, lines 19-29 and col 5, lines 1-3. The reference, if not explicitly teaching hydrolysis "essentially without mixing," clearly teaches away from additional mechanical mixing which would increase turbulence. The reference further teaches that the uniform flow is required for the preparation of hydrolyzates of analogous composition.

KOMAI exemplifies a hydrolysis temperature different from that recited in the claims. The reference also is drawn to sacchrification (breakdown to smaller products, such as glucose and maltose). However, it only in claim 10 that there is a limitation (producing plasma diluent) that would provide any molecular weight requirement. Moreover, the reference recognizes that it is known in the art to control the reaction velocity by varying conditions such as reaction temperature.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to conduct the process of SOMMERMEYER continuously using the KOMAI apparatus, comprising conveyance of the reaction mixture against the force of gravity, essentially without mixing, at the temperatures recited. The artisan would be motivated to use this apparatus for the advantage of conducting a continuous process and providing products with low polydispersity with a reasonable expectation of success.

KOMAI does not teach a (1) feeding device for the starch solution. The reference is also silent regarding (8) tempering unit(s) for the reactor(s). The reference describes the process as beginning with a pre-combined solution of starch and acid in container 13.



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It would have been obvious to one having ordinary skill in the art at the time the invention was made to add a (1) feeding device for the starch solution and (8) tempering unit(s) for the reactor(s). At some point before the reaction takes place, the acid and starch must be stored in separate containers. The artisan would be motivated to modify the KOMAI apparatus by adding a feeding device in order to convey the starch from a storage container to container 13. The artisan would be motivated to add tempering unit(s) to the reactor(s) in order to better control the temperature, and therefore the reaction products, at any given point in the process.

It would be obvious to one having ordinary skill in the art at the time the invention was made to conduct the fine hydrolysis with mixing. It would also be obvious to cool the hydrolysis mixture prior to neutralization in order to compensate for the heat generated in the exothermic acid-base neutralization reaction. The artisan would be motivated to mix the reaction mixture in order facilitate the change in the temperature (cooling).

It would be obvious to one having ordinary skill in the art to use the thus produced starch hydrolyzates formed in the process as a plasma expander, for the art-disclosed utility, as per SOMMERMEYER.

Claims 1, 2, 4-7, 9-15, 17, 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over SOMMERMEYER et al (US 5,218,108) in combination with KOMAI et al (US 3,446,664) in view of SMOLKA et al (US 4,562,086).

The invention is as set forth above. Claim 9 recites continuous ethoxylation.

SOMMERMEYER and KOMAI teach as set forth above. The combination of references does not teach continuous ethoxylation.

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SMOLKA teaches that starch etherification can be conducted in a continuous manner.

See col 4, lines 47-50.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to continuously ethoxylate the hydrolyzates prepared by the method of claim 1 for the preparation of plasma diluents. Continuous etherification is known in the art and would be within the scope of the artisan to determine necessary parameters for this reaction through routine experimentation. The artisan would be motivated to conduct the reaction continuously for the advantages for industrial production. In view of the fact that the neutralization step provides a reaction mixture (starch hydrolyzate + 1N NaOH) comprising two-thirds of the required components for the hydroxyethylation, the process would be particularly well suited to add this reaction as a continuous process in line with the continuous hydrolysis process. The ordinarily skilled worker would be motivated to add the continuous hydroxyethylation for overall convenience in providing a more compact process with a reasonable expectation of success.

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*Examiner's hours, phone & fax numbers*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (703) 308-4525. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (703) 308-4624, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

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Leigh C. Maier  
Patent Examiner  
March 25, 2004